UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: COVIDIEN HERNIA MESH PRODUCTS LIABILITY LITIGATION NO. II, This Document Relates To: All Cases	**MDL No. 1:22-md-03029-PBS**

COVIDIEN DEFENDANTS' STATEMENT OF THE CASE

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COVIDIEN DEFENDANTS' STATEMENT OF THE CASE

Use of synthetic mesh to repair hernia defects and reinforce weak tissue is the medical standard of care. Covidien[1] makes a variety of hernia mesh products, so that surgeons who repair hernias can choose the type of mesh best suited for each patient. Showing no regard for the medical standard of care or surgeons' need for options, Plaintiffs in this MDL challenge the design and safety of at least nine different hernia mesh products made by Covidien. Each of these meshes was cleared for use by the U.S. Food and Drug Administration ("FDA") and has been in clinical use for many years, without any recalls or regulatory action for any safety issues.

Plaintiffs assert a grab-bag of defect claims, attacking virtually every design variation among Covidien's meshes. For example, Plaintiffs allege, without any clinical basis, that it is a design defect for Covidien to make some meshes out of polyester, while also claiming it is a design defect for Covidien to make other meshes out of polypropylene. Yet almost all meshes on the market for the past thirty years have been made of one of these two polymers. Similarly, Plaintiffs allege that some of the pores in Covidien's meshes are too small, while others are too big; that both multi- and monofilament meshes are unsafe; that, despite a range of mesh weights/densities, none are adequate; and that, regardless of the design, any barrier on the mesh to prevent adhesion to internal organs is ineffective.

These claims are the latest in a host of litigation brought by the same plaintiffs' lawyers against other hernia mesh manufacturers. In this industry-wide litigation, Plaintiffs are alleging, in sum, that virtually every hernia mesh product on the market is defective. However, Covidien's

[1] The two defendant entities that manufacture Covidien hernia mesh products are Sofradim Production SAS (a French company) and Covidien LP. For ease of reference, we use the term "Covidien" throughout this memorandum.

meshes have been in clinical use for decades and are supported by a robust body of clinical experience and extensive testing demonstrating both their safety and efficacy.

Hernia surgery—like all surgery—is not without risks, including recurrence, reoperation, infection, pain, and bowel injury. These risks are present regardless of whether hernia mesh is used for the repair, and, importantly, no evidence exists that the use of Covidien hernia mesh products increases the risk of any of these complications. On the contrary, consistent with hernia mesh being the standard of care, it is well-established that the use of hernia mesh dramatically reduces the risk of hernia recurrence and the need for reoperation, and the clinical evidence shows that Covidien hernia mesh products perform as well as, or better than, other meshes on the market.

Nonetheless, Covidien faces a large number of lawsuits alleging its hernia mesh products are defective. Pending before the Court are approximately 100 such cases. This MDL follows two larger coordinated proceedings in Massachusetts and Minnesota state courts. Utilizing the discovery and pretrial procedures already in place in the Massachusetts state court proceeding, which began two years ago, will allow the Court and the parties to efficiently establish a process to bucket the claims pleaded here and test their merits through early motions practice and *Daubert* hearings.

The memorandum below provides more detailed background for the Court on hernias and hernia repair surgery, Covidien's hernia mesh products, Plaintiffs' claims and Covidien's defenses.

FACTUAL BACKGROUND

A. Hernias and Hernia Repair Surgery

A hernia is a common medical condition that affects more than four million people in the United States each year alone. Risk factors for developing hernias include obesity, pregnancy,

prior surgeries, and family history.[2] The term "abdominal hernia" refers generally to any defect in the abdominal muscles that results in a portion of a person's internal organs—often, the intestines of the bowel—protruding through the abdominal wall. Hernias can occur in a variety of locations in the abdomen and vary in size and severity. The location, size, and severity of a hernia can affect both its clinical course and how it is best treated.

If left untreated, a hernia can become incarcerated—meaning that abdominal contents become stuck in the abdominal wall causing severe pain—or strangulated—meaning that blood supply is cut off to a part of the bowel. Strangulation of the bowel is a surgical emergency that can result in disability or death.[3] Thus, while sometimes benign, the consequences of an untreated hernia can be severe and even life-threatening.

Surgery is the only treatment available to repair a hernia. Like all surgical procedures, hernia repair has well-known, inherent risks, regardless of whether, or which, mesh is used. According to the U.S. Food & Drug Administration ("FDA"), these risks include "pain, infection, hernia recurrence, scar-like tissue that sticks tissues together (adhesion), blockage of the large or small intestine (obstruction), bleeding, abnormal connection between organs, vessels, or intestines (fistula), fluid build-up at the surgical site (seroma), and a hole in neighboring tissues or organs (perforation)."[4] In particular, it is well-known that a significant percentage of hernias will recur within a few years after surgery. This risk of recurrence is ***lower*** when mesh is used and higher in patients who are obese or have large hernias.[5]

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[2] *See* FDA, Hernia Surgical Mesh Implants, https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/HerniaSurgicalMesh/default.htm (last updated Feb. 4, 2018).
[3] *Id.*
[4] *Id.*
[5] *Id.*

B. Hernia Mesh

Hernia mesh has been the standard of care for hernia repair for more than six decades. During this time, a large body of scientific evidence has established that the use of hernia mesh strengthens surgical repair, reduces the rate of hernia recurrence, and decreases the need for reoperation.[6] Clinical studies even suggest that surgical mesh improves patient outcomes and reduces recovery times.[7] For these reasons, the vast majority of surgeons now use mesh to repair all but the smallest hernias.[8] Indeed, leading hernia surgical societies in the United States and around the world recommend the use of mesh in virtually all hernia repair procedures.[9]

Today, a wide range of surgical meshes, sold by a number of different manufacturers, are available in the United States. These meshes differ in material, size, density, and other characteristics, allowing surgeons to choose—based on their experience and training—the most appropriate mesh to fit the needs of the individual patient and the specific repair procedure. The availability of varying design features in mesh is important because "the use of a single mesh

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[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] Ventral Hernia Working Group, et al. *Incisional ventral hernias: review of the literature and recommendations regarding the grading and technique of repair*. SURGERY 2010;148(3):544-58 ("[A]ll ventral hernia repairs should be reinforced with prosthetic repair materials. The current standard for reinforced hernia repair is synthetic mesh, which can reduce the risk for recurrence in many patients."); British Hernia Society, Mesh and your Hernia Repair (2018), https://www.britishherniasociety.org/british-hernia-society-mesh-safety-leaflet/ ("The use of mesh to repair the majority of hernias has been the preferred method in the UK and worldwide over 25 years."); Americas Hernia Society, Mesh Advisory Statement for Patients (Oct. 21, 2018), https://www.americanherniasociety.org/patient-education/mesh-advisory-statement ("The Americas Hernia Society (AHS) supports the use of appropriately selected mesh reinforcement for the vast majority of . . . hernias to reduce the risk of hernia recurrence."); THE SAGES MANUAL OF HERNIA SURGERY (S. Scott Davis Jr., Gregory Dakin, Andrew Bates, eds., 2d ed. 2019) ("Prosthetic mesh placement is now the standard of care for all but the smallest ventral hernias."); Bittner, R., et al., *Update of Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society (IEHS)) – Part A*, SURGICAL ENDOSCOPY 2019:33;3069-3139 ("[A]ll defects of the abdominal wall . . . and of whatever size should be repaired with the use of prosthetic mesh.").

design capable of functioning effectively in all scenarios is unrealistic."[10]

Over the past decade, based on FDA's extensive oversight of mesh products, there have been only a few isolated instances of hernia mesh products being recalled or withdrawn due to product design, packaging defects, or performance issues—most notably Davol's Composix Kugel Mesh and Ethicon's Physiomesh Flexible Composite Mesh.[11] Those problems stemmed from design features unique to the products at issue and led to extensive MDL proceedings. However, plaintiffs' counsel did not stop at those hernia mesh products and went on to launch industry-wide litigation targeting virtually ***all*** hernia mesh products, including meshes that have not been recalled or subject to any adverse regulatory action by FDA. None of Covidien's hernia mesh products at issue in this litigation have been recalled or subject to an adverse regulatory action related to safety.

C. Covidien Hernia Mesh Products

Covidien's hernia mesh portfolio illustrates how hernia mesh manufacturers have developed products adapted to meet surgeon needs, with prior mesh designs and clinical experience serving as the foundation for the next generation of meshes. Since 1990, Covidien has introduced more than 20 hernia mesh products with a variety of design features. In this MDL, nine different Covidien hernia mesh products presently are at issue: Parietex Composite ("PCO"), Parietex Optimized Composite ("PCOx"), Parietex Hydrophilic, Symbotex, Parietex ProGrip Self-Gripping ("ProGrip"), Parietex ProGrip Laparoscopic Self-Fixating ("Lap ProGrip"), Parietex Composite Ventral Patch ("PCO-VP"), Parietene, and Parietene DS.

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[10] *See* Surge Kalaba et al., *Design Strategies and Applications of Biomaterials and Devices for Hernia Repair*, BIOACTIVE MATERIALS 2016;1(1):2-17, at 5.

[11] *See, e.g.*, *In re Ethicon Physiomesh Flexible Composite Hernia Mesh Prods. Liab. Litig.*, No. 17-MD-02782 (N.D. Ga. filed June 2, 2017) (unique mesh design with anti-adhesion coatings on both sides led Ethicon to voluntarily withdraw mesh from market); *In re Physiomesh Litig. (Flexible Composite Mesh)*, No. 627 (N.J. Super. Ct. consolidated July 17, 2018) (same); *In re Kugel Mesh Hernia Patch Prods. Litig.*, No. 07-MD-1842 (D.R.I. consolidated June 22, 2007) (unique memory recoil ring broke in patients and led to FDA recalls in 2006 and 2007).

The chart below illustrates the distinct design features and uses of the products identified in Plaintiffs' Complaints to date.

PRODUCT	YEARS ON MARKET (US)	SAFETY-RELATED RECALLS	MATERIAL	PORE SIZE	WEIGHT / DENSITY	FILAMENT TYPE	BARRIER	HERNIA INDICATION
Parietex Hydrophilic	23	NONE	PET*	MACRO	HEAVY	MULTI	NO	INGUINAL & INCISIONAL
PCO	21	NONE	PET	MACRO	STANDARD	MULTI	YES	ALL
PCO-VP	10	NONE	PET	MACRO	STANDARD	MONO	YES	PARASTOMAL
PCOx	11	NONE	PET	MACRO	HEAVY	MULTI	YES	ALL
Symbotex	9	NONE	PET	MACRO	LIGHT	MONO	YES	ALL
Parietex ProGrip	14	NONE	PET	MACRO	STANDARD	MONO	NO	INGUINAL & INCISIONAL
Lap ProGrip	10	NONE	PET	MACRO	STANDARD	MONO	YES	INGUINAL
Parietene	23	NONE	PP**	MACRO	STANDARD	MONO	NO	ALL
Parietene DS	5	NONE	PP	MACRO	LIGHT	MONO	YES	ALL

*PET = polyethylene terephthalate, a type of polyester
**PP = polypropylene

1. Strong Safety Record

All Covidien hernia mesh products have been cleared for use through FDA's 510(k) process, which confirms that the meshes are safe, effective, and substantially equivalent to products already available on the market. Covidien has demonstrated the safety and efficacy of each mesh through extensive testing for biocompatibility, strength, performance, sterility, and

other qualities consistent with FDA requirements. After clearance, Covidien and the FDA conduct studies, closely monitor any complaints received, review the scientific literature, and evaluate other sources of information to ensure product safety. Covidien's robust monitoring program includes analyzing complaints from patients, providers, and publications for potential safety trends in addition to evaluating clinical studies, case reports, and surgeons' clinical experience.

2. Key Design Features

Each mesh product that Covidien manufactures incorporates a combination of design features that, working together, make the mesh suitable for different patient needs and surgical procedures. All of these characteristics interact with each other and contribute to the ultimate performance of the mesh. There is no "one size fits all" hernia mesh—no single set of design features are appropriate for every patient or every clinical situation.

There are five primary design characteristics that vary across the meshes at issue and provide surgeons with an array of treatment options depending on the hernia, the patient, and the surgeon's personal preferences. These are material, filament, pore size, weight, and barrier. Certain mesh products also contain other unique features designed to meet specific surgical needs. Parietex ProGrip and Lap ProGrip are two such meshes, containing a "microgrip" feature.

Material. The products at issue in this MDL consist of synthetic meshes made from polyester or polypropylene. Five meshes (PCO, PCOx, Parietex Hydrophilic, Parietex ProGrip, Lap ProGrip, Symbotex, and PCO-VP) are composed of polyester, while two meshes (Parietene and Parietene DS) are composed of polypropylene. These materials differ based on surgeon preference and the materials' effects on handling properties. For example, some surgeons report a preference for polyester mesh for laparoscopic procedures because it is pliable and unfolds more easily than polypropylene mesh. Both polyester and polypropylene have been used safely in hernia mesh products and other implantable medical devices (for example, cardiac stents) for

decades, and neither the FDA nor the broader surgical community has raised concerns about the use of either material for this purpose. Approximately 90% of hernia mesh products on the market today are made from either polyester or polypropylene.

Filament. Covidien hernia meshes are designed as either multifilament or monofilament. Multifilament meshes are knitted from multiple fibers woven together in a manner similar to a rope, whereas monofilament meshes are knitted from single fibers. These structures contribute to a mesh's handling properties, as multifilament mesh tends to be softer and more pliable, whereas monofilament mesh offers more stiffness. Three meshes (PCO, PCOx, and Parietex Hydrophilic) are multifilament, while six meshes (Parietex ProGrip, Lap ProGrip, PCO-VP, Symbotex, Parietene, and Parietene DS) are monofilament.

Pore Size. The pores within a hernia mesh enable tissue to grow and anchor the mesh in place, helping prevent a hernia from recurring. Pores also allow fluids to pass through the mesh, lowering the risk of fluid build-up—a common side effect of hernia surgery known as a seroma—and reducing the risk of infection. The size of the pores influences a mesh's mechanical strength and propensity for tissue integration as well. The Covidien meshes at issue are large pore meshes—ranging in size from 1.3 to 3.0 millimeters in diameter—which, the scientific evidence suggests, is a range the helps promote tissue ingrowth and minimize the risk of pain.

Weight/Density. The weight or density of a hernia mesh refers to the amount of material in the mesh. Meshes fall on a continuum depending on their particular design. The choice of the appropriate mesh weight is a clinical decision left to the surgeon. Surgeons might select heavier meshes when repairing large, complex hernias or hernias in patients who are overweight. Conversely, surgeons might select a lighter-weight mesh to repair a smaller hernia or for a

patient who is smaller or less active. Regardless, surgeons require a range of meshes with different weights to be able to select the most appropriate mesh for each individual patient. As detailed in the chart above, Covidien's hernia mesh products range from light to heavyweight.

Barrier. Depending on the location and size of a hernia, surgeons may perform repairs using the intraperitoneal onlay mesh ("IPOM") procedure. Because this procedure places the mesh in direct contact with the bowel, manufacturers, including Covidien, developed hernia mesh products containing a barrier layer or coating on the side of the mesh that faces the bowel to minimize the risk of scar tissue—known as adhesions—developing between the mesh and the bowel. Among the nine products at issue in this litigation, six have barriers (PCO, PCOx, PCO-VP, Symbotex, Lap ProGrip, and Parietene DS).

The presence of a barrier is most important for the first five to seven days after an IPOM surgery, before the body has a chance to heal and develop a new layer of cells (or peritoneum) between the mesh and the bowel. Once this occurs, the barrier is no longer needed, so it is designed to be absorbed by the body during the healing process. All but one of Covidien's barrier meshes are comprised of a collagen barrier that the body fully absorbs about 30 days after surgery. Parietene DS has a synthetic barrier that fully absorbs within 105 days and provides an alternative for patients who may wish to avoid products containing animal byproducts such as collagen.

ProGrip "Microgrips." Covidien's Parietex ProGrip and Lap ProGrip products have a unique microgrip feature, consisting of thousands of tiny, self-fixating, and resorbable synthetic grips on one side of the mesh that disappear over time. The microgrips allow surgeons to place Parietex ProGrip and Lap ProGrip without the use of a fixation device like tacks or sutures and are intended to help reduce surgery time and post-operative recovery. Meshes with microgrips

can attach directly to the patients' tissue, and the microgrips slowly reabsorb over the course of approximately 18 months as tissue integrates into the mesh, reinforcing the hernia repair.

D. Plaintiffs' Alleged Injuries

Plaintiffs' alleged injuries—pain, recurrence, adhesions, infection, migration, and bowel complications—all are well-recognized complications of hernia repair surgery that are universally known by surgeons and routinely told by surgeons to patients. These complications can occur with or without the use of mesh and regardless of the type of mesh used. Indeed, a large body of scientific evidence suggests that the use of mesh in hernia repairs helps to ***reduce*** several of these complications (most notably recurrence) and improve patient outcomes.[12] Further, several factors including a patient's health history and lifestyle strongly impact the likelihood of these complications occurring. For example, obesity increases the likelihood for recurrence and smoking impairs wound healing, increasing the likelihood of infection.[13]

Surgeons are aware of the common complications of hernia surgery and the risk associated with the use of hernia mesh based on their professional training and experience, starting in medical school and progressing through their residency training and clinical practice. These potential risks also are outlined in the Instructions for Use ("IFU") that accompany all Covidien mesh products. As shown in the chart below, Plaintiffs overwhelmingly allege they suffered common, expected, and warned-about complications associated with hernia surgery.

Alleged Injury	Number and Percent of Cases
Pain	59 (62%)
Adhesions	49 (52%)
Infection	34 (36%)
Recurrence	20 (21%)

[12] *See* FDA, Hernia Surgical Mesh Implants, https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/HerniaSurgicalMesh/default.htm (last updated Feb. 4, 2018).
[13] *See id.*

Bowel Complications	17 (18%)

Rather than attributing their injuries to a myriad of potential patient and surgical factors, Plaintiffs allege that those injuries were caused by some design defect in each of Covidien's hernia mesh products.

E. Other Hernia Mesh Litigation

1. Covidien Hernia Mesh Litigation

As the Court is aware, this MDL is one of three coordinated proceedings concerning products liability claims related to Covidien's hernia mesh products. In July 2020, the Superior Court of Massachusetts coordinated all hernia mesh cases filed in that court in Middlesex County, now before the Honorable Christopher Barry-Smith. *See Bettie Ann Smith v. Covidien LP, et al.*, Civil Action No. 1781CV01845 (Lead Case) (the "MA proceeding"). Today, the MA proceeding consists of more than 5,000 suits and includes all of the same products at issue in this MDL (and more). Defendants successfully moved to dismiss deceptive trade practices and punitive damages claims in three representative complaints selected by the parties for motion practice on the pleadings. Plaintiffs' remaining claims include strict liability, negligent design defect, and failure to warn. Unlike here, plaintiffs in the MA proceeding do not allege manufacturing defect claims. Document discovery is well underway, with case-specific discovery set to begin after the parties select cases for an initial bellwether discovery pool in early January 2023.

The second coordinated proceeding is before Judge James A. Moore in the District Court for Hennepin County, Minnesota. *McCauley, et al. v. Medtronic, Inc., et al.*, No. 27-CV-14780. Formed in December 2021, it consists of 29 suits involving 352 plaintiffs and also includes many of the same products at issue in the MDL. The litigation is in the early stages, with no master pleadings or early motion practice, and no discovery to date.

Prior to the formation of this MDL, Covidien litigated more than 30 single-plaintiff cases filed in different federal district courts across the country. In 19 of those cases, the district court dismissed the plaintiffs' allegations in their entirety on the merits, finding that plaintiffs—often after multiple attempts—failed to assert facts sufficient to support their design defect, manufacturing defect, and failure to warn claims.[14] Among the handful of cases that progressed beyond the pleadings stage, all were dismissed, most on summary judgment. *See Avendt v. Covidien Inc.*, 262 F. Supp. 3d 493 (E.D. Mich. 2017) (granting summary judgment for Covidien); *Emery v. Medtronic, Inc.*, No. 4:18-cv-358 (S.D. Tex. Apr. 24, 2019), ECF No. 66, *aff'd* 793 F. App'x. 293 (5th Cir. 2019) (same); *Northrup v. Covidien LP*, No. 5:20-cv-355 (C.D. Cal. Nov. 24, 2021), ECF No. 100 (same and excluding plaintiff's specific causation expert on *Daubert* grounds).

2. Litigation Against Other Hernia Mesh Manufacturers

There has been a series of litigations involving hernia mesh products manufactured by other companies, much of which was brought by the same plaintiffs' counsel. Beginning in 2007, the Judicial Panel for Multidistrict Litigation ("JPML") centralized personal injury actions relating to the recall of Kugel Hernia Patch manufactured by C.R. Bard, Inc. and Davol, Inc., *In re: Kugel*

[14] *See, e.g., Sparks v. Medtronic, Inc. et al.*, No. 8:20-cv-03074-SCB-TGW (M.D. Fla. June 28, 2021) (dismissing complaint in its entirety and with prejudice); *Dunham v. Covidien, LP*, No. 19-cv-02855 (S.D.N.Y. Oct. 9, 2020), ECF No. 41 (same); *Krulewich v. Covidien L.P.*, No. 19-cv-02857 (S.D.N.Y. Oct. 9, 2020), ECF No. 34 (same); *Taylor v. Medtronic, Inc.*, No. 18-cv-1201, 2020 WL 886118 (N.D.N.Y Feb. 24, 2020) (same); *Cofresi v. Medtronic*, No. 19-cv-1222 (W.D. Tex. Mar. 30, 2020), ECF No. 22 (dismissing complaint in its entirety); *Kelly v. Covidien, Inc.*, No. 19-cv-05497 (S.D.N.Y. Jan. 7, 2020), ECF No. 16 (same); *Meredith v. Medtronic, Inc.*, No. 18-cv-00127 (S.D. Iowa Oct. 25, 2019), ECF No. 56 (same); *Green v. Covidien LP*, No. 18-cv-02939 (S.D.N.Y. Aug. 30, 2019), ECF No. 22 (same); *Soutner v. Covidien, LP*, No. 17-cv-02178, 2019 WL 3801438 (M.D. Pa. Aug. 13, 2019) (same); *Nowell v. Medtronic, Inc.*, 372 F. Supp. 3d 1166 (D.N.M. 2019) (same); *Kennedy v. Covidien, LP*, No. 18-cv-01907, 2019 WL 1429979 (S.D.N.Y. Mar. 29, 2019) (same); *Barnes v. Medtronic, PLC*, No. 17-cv-14194, 2019 WL 1353880 (E.D. Mich. Mar. 26, 2019) (same); *Rincon v. Covidien*, No. 16-CV-10033, 2017 WL 2242969 (S.D.N.Y. May 22, 2017) (same).

Mesh Hernia Patch Prod. Liab. Litig., 493 F. Supp. 2d 1371 (J.P.M.L. 2007). A decade later, the JPML centralized claims alleging defects in Atrium Medical Corporation's C-QUR hernia mesh, *In re: Atrium Medical Corp. C-QUR Mesh Prods. Liab. Litig.*, 223 F. Supp. 3d 1355 (J.P.M.L. 2016). In 2017, the JPML did the same for actions alleging defects in the withdrawn Physiomesh product, manufactured by Ethicon, Inc. and Johnson & Johnson, *In re: Ethicon Physiomesh Flexible Composite Hernia Mesh Prods. Liab. Litig*., 254 F. Supp. 3d 1381 (J.P.M.L. 2017). Today, these three MDLs are mostly resolved.

In 2018, the JPML centralized actions pertaining to a variety of polypropylene-based hernia mesh products manufactured by Bard and Davol, *In re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, 316 F. Supp. 3d 1380 (2018). Lead Counsel for Plaintiffs in this MDL served as trial counsel for plaintiffs in the first two bellwether cases in the Bard polypropylene MDL. In the first bellwether trial, *Johns v. C.R. Bard, et al.*, the jury returned a defense verdict, finding that defendants were not liable for injuries the plaintiff alleged resulted from mesh defects. No. 2:18-cv-01509 (S.D. Ohio Sept. 8, 2021), ECF No. 552. In the second bellwether trial, *Milanesi, et al. v. C.R. Bard, et al.*, the jury found in favor of plaintiffs only on their negligent design defect claim while rejecting plaintiffs' strict liability design defect, failure to warn, negligent misrepresentation, and fraudulent misrepresentation claims, and awarded $250,000 in damages. No. 2:18-cv-01320 (S.D. Ohio, Apr. 15, 2022), ECF No. 381. Based on the modest damages award, however, the plaintiffs have since moved the court for a new trial on damages. *Milanesi*, No. 2:18-cv-01320, (S.D. Ohio, May 13, 2022), ECF No. 385.

LEGAL CLAIMS AND DEFENSES

A. Plaintiffs' Claims

Plaintiffs allege strict liability and negligent design defect, manufacturing defect, and failure to warn claims, as well as breach of warranty, fraudulent concealment, and negligent

misrepresentation. Approximately 90% of the Complaints pending in the MDL were filed by one of two plaintiffs' firms—Levin, Papantonio, Rafferty, Proctor, Buchanan, O'Brien, Barr & Mougey, P.A or Fleming, Nolen & Jez, LLP. Though the Complaints allege use of at least nine distinct products, the factual allegations and legal claims they assert are nearly identical. Plaintiffs' one-size-fits-all approach creates inconsistencies, which highlights their failure to state a claim pursuant to Rule 12(b)(6). Indeed, many of the Complaints allege as safer alternative designs the features of some Covidien hernia mesh products that other Complaints allege are defective.

Design Defect. Plaintiffs assert that one or more characteristics of the Covidien hernia mesh that their surgeons chose to use to repair their hernias constitutes a fundamental defect in the mesh's design, rendering the product unfit for its intended use and causing Plaintiffs' injuries. *See, e.g.*, *Easom v. Covidien, Inc., et al.*, No. 1:21-cv-11985, ECF No. 1 ¶¶ 49–50 (D. Mass. Dec. 8, 2021). In cases involving meshes made of polyester, Plaintiffs allege that the polyester polymer is defective because it is brittle and causes an inflammatory reaction resulting in injury. *Id.* ¶¶ 42–44. Plaintiffs allege that polypropylene is a safer alternative that would have reduced the severity and duration of their injuries. *Id.* ¶ 92 ("[O]ther safer feasible alternative designs for hernia mesh products that would have reduced the likelihood, severity, frequency and duration of the injuries Plaintiff suffered include utilizing the polymer polypropylene as the permanent polymer grafting material."). Simultaneously, Plaintiffs assert that Covidien's Parietene products, made of polypropylene, are defective, asserting nearly identical allegations that polypropylene is brittle and causes an inflammatory reaction. *See, e.g.*, *Oremeno, et al., v. Covidien, Inc., et al.*, No. 1:22-cv-10778, ECF No. 1 ¶¶ 43–44 (D. Mass. May 20, 2022). Amazingly, these copy-cat Complaints also allege that polypropylene is a safer alternative design. *Id.* ¶ 130 ("[O]ther safer feasible alternative designs for hernia mesh products that would

have reduced the likelihood, severity, frequency and duration of the injuries Plaintiff suffered include utilizing the polymer polypropylene as the permanent polymer grafting material."). These inconsistent allegations epitomize Plaintiffs' "heads I win, tails you lose" approach to the litigation and demonstrate Plaintiffs' inability to point to a safer alternative design.

Manufacturing Defect. Plaintiffs also allege that a flaw in the manufacturing process caused the hernia mesh to deviate from Covidien's design and manufacturing specifications. *See, e.g., Easom*, No. 1:21-cv-11985, ECF No. 1 ¶¶ 104–123. Among their claims, Plaintiffs assert that Covidien utilized "adulterated" polyester and collagen film and did not conduct proper quality controls and testing in the manufacturing process. *Id.* ¶¶ 107–108, 110. However, nowhere do they allege how the polyester and collagen film allegedly deviated from their specifications (or how they were "adulterated"), nor do they allege any facts identifying from which quality controls and/or testing Covidien allegedly deviated.

Failure to Warn. Plaintiffs allege that Covidien failed to provide sufficient warnings and instructions that would have put Plaintiffs, their health care providers, and the general public on notice of adverse effects associated with the use of their hernia mesh products. *See, e.g., id.* ¶¶ 124–137. Plaintiffs allege a laundry list of purported warnings that should have been provided, most of which have no relevance to the particular product the Plaintiff claims to have used. *Id.* ¶ 127(a)–(ll). Further, the risks associated with surgical hernia repair and the use of hernia mesh are well known to surgeons.

Breach of Warranty. Plaintiffs claim that Covidien breached express warranties that their hernia mesh products were safe for use and fit for their intended purposes because the products were defective, did not include adequate information about associated risks, and were not as safe or effective as Covidien represented. *See, e.g., id.* ¶¶ 148–159. Plaintiffs also assert

that Covidien breached implied warranties of merchantability, on the similar basis that their hernia mesh products were not of the quality, safety, and fitness Covidien impliedly warranted. *Id*. ¶¶ 160–174. Plaintiffs claim that they, or their physicians, relied on Covidien's warranties as the basis for consenting to have Covidien's hernia mesh products placed.

***Fraudulent Concealment and Negligent Misrepresentation*.** Plaintiffs allege that Defendants fraudulently withheld and concealed information about their hernia mesh products pertaining to the products' efficacy and the risks of injury associated with them. *See, e.g.*, *Beymer v. Covidien, Inc., et al.*, 1:22-cv-10100, ECF No. 1 ¶¶ 197–199. Plaintiffs claim that they and/or their surgeons were induced to use Defendants' hernia mesh products based on these alleged misrepresentations or omissions. *Id*. ¶¶ 204–205. Plaintiffs likewise allege that Defendants negligently materially misrepresented the safety and efficacy of their products to the medical community, inducing Plaintiffs and their surgeons to purchase and place Defendants' hernia mesh products. *Id*. ¶¶ 219–224.

B. Covidien's Defenses

Covidien has a number of defenses it expects to assert to seek dismissal of the cases, including through early Rule 12(b)(6) and Rule 56 motion practice and/or *Daubert* challenges for particular products and/or alleged injuries. These defenses include statute of limitations, lack of a design defect and/or safer alternative design, lack of a deviation from intended specifications, lack of a warnings defect, and failure to establish causation.

***Statute of Limitations*.** Based on a preliminary analysis of the Complaints, Covidien believes as many as one-third of the cases in the docket may be time-barred. Covidien intends to assert a statute of limitations defense based upon the limitations periods applicable to Plaintiffs in their states of residence, possibly through one or more omnibus motions. Plaintiffs were placed on notice of the claims they have now asserted at the onset of experiencing complications

that are well-known and warned of in the IFU that accompanies each Covidien hernia mesh product. *See Nowell v. Medtronic Inc.*, 372 F. Supp. 3d 1166 (D.N.M. 2019), *aff'd*, No. 19-2073, 2021 WL 4979300 (10th Cir. Oct. 27, 2021) (dismissing hernia mesh complaint with prejudice on statute of limitations grounds); *Soutner*, 2019 WL 3801438 (same).

Lack of Design Defect and/or Safer Alternative Design. Plaintiffs cannot establish that the design of any Covidien hernia mesh product is defective because those claims are unsupported by the scientific evidence and decades of real-world use of the products by surgeons, and there is no evidence of any recalls or adverse regulatory action related to safety. In addition, most states require evidence of a safer alternative design, either as an element to be proven or as part of a risk-utility assessment, to establish a design defect. *See Branham v. Ford Motor Co.*, 390 S.C. 203, n.11 (2010); Restatement (Third) of Torts: Products Liability § 2(b) (1998); *see also Dunham*, 2019 WL 2461806 (dismissing hernia mesh design defect claim for failure to allege feasible alternative design); *Meredith*, 2019 WL 6330677 (same); *Barnes*, 2019 WL 1353880 (same). Plaintiffs do not agree on one uniform safer alternative design, and in some cases they take contradictory positions in identifying design defects and what would be a better design. For example, Plaintiffs cannot reconcile asserting that polypropylene is a defective material while simultaneously holding polypropylene out to be the safer alternative design in other cases within the same MDL. Moreover, by attacking both polyester and polypropylene—the two materials from which the vast majority of hernia meshes in the United States are made today—Plaintiffs effectively are taking the position that there is no safe, alternative hernia mesh product on the market, which flies in the face of the well-established standard of care followed by surgeons across the country. *See Kennedy v. Covidien, LP*, 2019

WL 1429979, at *3–4 ("[A]lleging that the product should not be used at all is insufficient to satisfy the feasible alternative design element.").

No Deviation from Intended Specifications. Plaintiffs' manufacturing defect claims require a showing that Covidien's hernia mesh products deviated from their design specifications. Plaintiffs have no basis to assert that the mesh products they received differed in any way from their FDA-cleared specifications and can point to no product recalls, withdrawals, or safety signals reflecting a defect in manufacturing. *See Green*, 2021 WL 1198833, at *2 (S.D.N.Y. Mar. 30, 2021) (dismissing mesh manufacturing defect claim because plaintiff "did not plead facts showing how Defendant's manufacturing process was flawed, or in what way the mesh in question deviated from Defendant's design"); *Krulewich*, 498 F. Supp. 3d 566 (same).

Adequate Warnings. Chief among the information and materials about Covidien's hernia mesh products available to physicians are Covidien's FDA-cleared Instructions for Use ("IFUs"). IFUs detail the features of the mesh, the types of procedures for which it has been cleared for use by FDA, how to position it during procedures, possible complications from use, potential contraindications, and other warnings and precautions. Covidien's IFUs adequately warned of complications associated with its hernia mesh products, which largely capture the injuries Plaintiffs allege here. *See Green*, 2021 WL 1198833, at *7; *Krulewich*, 498 F. Supp. 3d at 577; *Kennedy*, 2019 WL 1429979 at *5.

Further, many jurisdictions hold that failure to warn claims are subject to a "learned intermediary" defense, which provides that a medical device manufacturer owes no duty directly to a patient to warn of a particular risk; instead, the manufacturer satisfies its duty by providing warnings to the patient's physician. *See, e.g.*, *Calisi v. Abbott Lab'ys*, No. CIV.A. 11-10671-

DJC, 2013 WL 5441355, at *3 (D. Mass. Sep. 27, 2013). Covidien satisfies its duty to warn in making its product-specific IFUs available to physicians.

No Causation*.** There is no reliable scientific evidence that Covidien's hernia mesh products cause certain alleged injuries, such as recurrence. Surgeons continue to use hernia mesh for all but the smallest hernia repairs because of the overwhelming scientific evidence demonstrating that hernia mesh ***reduces the risk of recurrence compared to no mesh. In addition, Plaintiffs cannot show that Covidien's hernia mesh products caused their specific injuries because there are many alternative explanations for the complications they allege. As explained above, Plaintiffs' alleged injuries are well-known by the scientific community to be associated with hernia repair surgery, regardless of whether mesh is used. These same complications also can arise from a variety of patient health and lifestyle factors. Plaintiffs simply cannot demonstrate that some defect specific to Covidien's hernia mesh products resulted in their injuries. *See Krulewich*, 498 F. Supp. 3d at 576 ("As courts considering similar issues have concluded, the plaintiffs in this case 'do[] not address the numerous plausible alternative explanations for [plaintiff's] medical problems, including natural complications from his hernia disease or the development of a new hernia.'") (internal citation omitted); *Dunham*, 2019 WL 2461806 at *2 ("Yet pain and recurring hernias are known complications of hernia repair surgery, regardless of whether mesh is used, so the possibility of other causes has not been excluded . . .")*; see also Sparks*, 2021 WL 2649235, at *2; *Green*, 2021 WL 1198833 at *5; Rincon, 2017 WL 2242969, at *1.

KEY CASE MANAGEMENT CONSIDERATIONS

Given the significant overlap in the products and claims at issue in the MA coordinated proceeding and the MDL, Covidien believes it would be efficient and beneficial to all the parties to utilize and produce in this MDL the discovery that already has been produced in the MA

coordinated proceeding. To date, Covidien has produced hundreds of thousands of pages of documents in the MA coordinated proceeding, including the design history files, 510(k) and other regulatory files, organizational charts, and complaint reports. Further, because depositions of Covidien employees have not yet been taken in the MA coordinated proceeding, Covidien proposes that these employees' depositions be taken jointly to the extent possible and to conserve resources and reduce the burden on the witnesses.

As discussed above, Covidien has successfully litigated and achieved dismissal of many of the same claims that Plaintiffs assert here in other federal courts across the country. *See supra* p. 12, n. 14. For this reason, Covidien believes it would be fruitful to narrow the claims at issue in the MDL through a master complaint, a procedural vehicle used in almost all current product liability MDLs, which Covidien would have the opportunity to challenge through a motion to dismiss. Covidien also respectfully proposes streamlining cases that can be evaluated on the merits through early motion practice as the litigation develops.

CONCLUSION

Covidien looks forward to working with Plaintiffs and the Court to coordinate and efficiently resolve these cases.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Loren H. Brown, certify that on September 13, 2022 a true and correct copy of the foregoing document was served on all counsel of record by filing it with the courts Nextgen CM/ECF system.

/s/ Loren H. Brown
Loren H. Brown